PTO/SB/08a (04-07)

JAN 1-0 2008

Approved for use through 09/30/2007, ONB 0651-0031

U.S. Patent and Trademan, Office, U.S. DPARTMENT OF COMMERCE

U.S. Patent and Trademan, Office, U.S. DPARTMENT OF COMMERCE

Specific the Papervork Reduction Act of 1995, no persons are required to respond to a collection of information unities it contains a suid OMB control number.

## Substitute from 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)
Sheet 1 of 7

|                      |         | Document Number                            |                                | Name of Patentee or Applicant of |  |
|----------------------|---------|--|--------------------------------|----------------------------------|--|
| Examiner<br>Initials | No.1    | Number - Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Cited Document                   | Pages, Columns, Lines, Where Relevan<br>Passages or Relevant<br>Figures Appear |
|                      |         | US-3,531,561                               | 09-29-1970                     | Trebu                            |  |
|                      |         | US-3,636,956                               | 01-25-1972                     | Schneider                        |  |
|                      |         | US-3,736,646                               | 06-05-1973                     | Schmitt                          |  |
|                      |         | US-3,797,499                               | 03-19-1974                     | Schneider                        |  |
|                      |         | US-4,137,921                               | 02-06-1979                     | Okuzumi                          |  |
|                      |         | US-4,181,983                               | 01-08-1980                     | Kulkami                          |  |
|                      |         | US*4,523,591                               | 06-18-1985                     | Kaplan                           |  |
|                      |         | US-4,539,981                               | 09-10-1985                     | Tung                             |  |
|                      |         | US-4,636,215                               | 01-13-1987                     | Schwartz                         |  |
|                      |         | US-4,938,763                               | 07-03-1990                     | Dunn, et al.                     |  |
|                      |         | US-5,108,755                               | 04-28-1992                     | Daniels, et al.                  |  |
|                      |         | US-5,192,301                               | 03-09-1993                     | Kamika                           |  |
|                      |         | US-5,266,608                               | 11-30-1993                     | Katz, et al.                     |  |
|                      |         | US-5,275,601                               | 01-04-1994                     | Gogolewski, et al.               |  |
|                      |         | US-5,333,624                               | 08-02-1994                     | Tovey                            |  |
|                      | T       | US-5,360,448                               | 11-01-1994                     | Thramann                         |  |
| _                    |         | US-5,364,400                               | 11-15-1994                     | Rego, Jr., et al.                |  |
|                      |         | US-5,417,712                               | 05-23-1995                     | Whittaker                        |  |
|                      |         | US-5,437,918                               | 08-01-1995                     | Taniguchi                        |  |
|                      |         | US-5,441,515                               | 08-15-1995                     | Khosravi                         |  |
|                      |         | US-5,470,334                               | 11-28-1995                     | Ross, et al.                     |  |
|                      | · · · · | US-5,582,704                               | 10-08-1996                     | Tamminmaki, et al.               |  |
|                      |         | US-5,633,002                               | 05-27-1997                     | Stricker                         |  |
|                      |         | US-5,634,938                               | 06-03-1997                     | Linden                           |  |
|                      |         | US-5,660,846                               | 08-26-1997                     | Cheikh                           |  |
|                      |         | US-5,870,181                               | 09-23-1997                     | Healy                            |  |
|                      |         | US-5,690,671                               | 11-25-1997                     | McGurk                           |  |
|                      |         | US-5,695,497                               | 12-09-1997                     | Stahelin                         |  |
|                      |         | US-5,716,410                               | 02-10-1998                     | Wang, et al.                     |  |
|                      |         | US-5,716,413                               | 02-10-1998                     | Walter, et al.                   |  |
|                      |         | US-5,733,330                               | 03-31-1998                     | Cox                              |  |
|                      |         | US-5,760,118                               | 06-02-1998                     | Sinclair                         |  |
|                      |         | US-5,766,239                               | 06-16-1998                     | Cox                              |  |
|                      |         | US-5,766,618                               | 06-16-1998                     | Laurencin, et al.                |  |
|                      |         | US-5,792,400                               | 08-11-1998                     | Talja, et al.                    |  |
|                      |         | US-5,834,582                               | 11-10-1998                     | Sinclair                         |  |
|                      |         | US-5.837.276                               | 11-17-1998                     | Camevale                         |  |

| Examiner<br>Signature | <br>Date<br>Considered |  |
|-----------------------|------------------------|--|
| Signature             |                        |  |

EXAMINER: Initial if reference considered, whether or not citation is in corconsidered. Include copy of this form with next communication to applicant.

Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a Substitute for form 1449A/PTO

Complete if Known

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

| equired to respond to a collection of | of information unless it contains a valid CIMB control to | number. |
|---------------------------------------|---|---------|
|                                       | Complete if Known   | 7       |
| Application Number                    | 10/776409   |         |
| Filing Date                           | February 10, 2004   |         |
| First Named Inventor                  | Kelman  |         |
| Art Unit                              | 3739  |         |
| Examiner Name                         | Reimers, Annette R.                                       |         |
| Attorney Docket Number                | 10557/296452  |         |

|                     |  |   | U.S. PATENT I                  |  |   |  |
|---------------------|--|---|--------------------------------|--|---|--|
| Examiner Initials * | Cite<br>No.1                                     | Document Number  Number - Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant<br>Figures Appear |  |
|                     |  | US-5.893.850  | 04-13-1999                     | Cachia   | i igo ta Appear   |  |
|                     | <del>                                     </del> | US-5,904,658  | 05-18-1999                     | Niederauer, et al.                                 |   |  |
|                     |  | US-5,908,918  | 06-01-1999                     | Chen   |   |  |
|                     |  | US-5,968,092  | 10-19-1999                     | Buscemi  |   |  |
|                     | <b>-</b>   | US-5.980.564  | 11-09-1999                     | Stinson  |   |  |
|                     | -  | US-6.001.100  | 12-14-1999                     | Sherman, et al.                                    |   |  |
|                     |  | US-6.001,101  | 12-14-1999                     | Augagneur, et al.                                  |   |  |
|                     | <u> </u>   | US-6,005,161  | 12-21-1999                     | Brekke, et al.                                     |   |  |
|                     |  | US-6.113.624  | 09-05-2000                     | Bezwada, et al.                                    |   |  |
|                     | <b>—</b>   | US-6,160,084  | 12-12-2000                     | Langer, et al.                                     |   |  |
|                     | <b>—</b>   | US-6.162.225  | 12-19-2000                     | Gertzman, et al.                                   |   |  |
|                     |  | US-6,203,573  | 03-20-2001                     | Walter, et al.                                     |   |  |
|                     | 1  | US-6,248,108  | 06-19-2001                     | Tormala  |   |  |
|                     |  | US-6.283.973  | 09-04-2001                     | Hubbard, et al.                                    |   |  |
|                     | -  | US-6.293.950  | 09-25-2001                     | Lynch, el al.                                      |   |  |
|                     |  | US-6,344,498  | 02-05-2002                     | Niederauer, et al.                                 |   |  |
|                     |  | US-6,375,485  | 04-23-2002                     | Engman, et al.                                     |   |  |
| -                   |  | US-6.436.136  | 08-20-2002                     | Flodin, et al.                                     |   |  |
|                     |  | US-6,468,277  | 10-22-2002                     | Justin, et al.                                     |   |  |
|                     |  | US-6.503.278  | 01-07-2003                     | Pohjonen   |   |  |
|                     |  | US-6,511,511  | 01-28-2003                     | Slivka, et al.                                     |   |  |
|                     |  | US-6.514,288  | 02-04-2003                     | Leatherbury, et al.                                |   |  |
|                     |  | US-6,565,606  | 05-20-2003                     | Bruce, et al.                                      |   |  |
|                     |  | US-6,652,582  | 11-25-2003                     | Stinson  |   |  |
|                     |  | US-6.783.712  | 08-31-2004                     | Slivka, et al.                                     |   |  |
|                     |  | US-6,841,111  | 01-11-2005                     | Rickner, et al.                                    |   |  |
|                     |  | US-6.918.321 B2   | 07-12-2005                     | TehHuisen, et al.                                  |   |  |
|                     |  | US-7,033,603  | 04-25-2006                     | Nelson, et al.                                     |   |  |
|                     |  | US-7.261.734  | 08-28-2007                     | Gellman, et al.                                    |   |  |
|                     |  | US-7,281,716  | 08-28-2007                     | Strobel, et al.                                    |   |  |
|                     |  | US-7,268,205  | 09-11-2007                     | Williams, et al.                                   |   |  |
|                     | _  | US-7,270,813  | 09-18-2007                     | Shimp, et al.                                      |   |  |
|                     |  | US-2002/0029043   | 03-07-2002                     | Ahrens, et al.                                     |   |  |
|                     |  | US-2003/0114937 A1  | 06-19-2003                     | Leatherbury, et al.                                |   |  |
|                     |  | US-2003/0125745   | 07-03-2003                     | Tseng, et al.                                      |   |  |
|                     |  | US-2004/0193154 A1  | 09-30-2004                     | Leatherbury, et al.                                |   |  |
|                     |  | US-2004/0241203 A1  | 12-02-2004                     | Shakesheff, et al.                                 |   |  |
|                     |  | US-2004/0258732   | 12-23-2004                     | Shikinami  |   |  |
|                     |  | US-2004/0267263   | 12-30-2004                     | May  |   |  |

| Examiner<br>Signature | Date<br>Considered |  |
|-----------------------|--------------------|--|
|                       |                    |  |

\*EXAMINER: Initial if reference considered, whether or not citation is in c considered. Include copy of this form with next communication to applicant.

PTO/SR/089 (04-07)

Approved for use through 09/30/2007. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Substitu | ate for form 1449A | PTO       |            |                        | Complete if Known   |  |
|----------|--------------------|-----------|------------|------------------------|---------------------|--|
|          |                    |           |            | Application Number     | 10/776409           |  |
| INF      | ORMATIO            | N DIS     | CLOSURE    | Filing Date            | February 10, 2004   |  |
| STA      | TEMENT             | BY A      | PPLICANT   | First Named Inventor   | Kelman              |  |
|          |                    |           |            | Art Unit               | 3739                |  |
|          | (Use as many       | sheets as | necessary) | Examiner Name          | Reimers, Annette R. |  |
| Sheet    | 3                  | of        | 7          | Attorney Docket Number | 10557/296452        |  |

|                        |             |                    | U.S. PATENT D                  | OCUMENTS   |   |
|------------------------|-------------|--------------------|--------------------------------|--|---|
| Examiner<br>Initials * | Cite<br>No. | Document Number    | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant<br>Figures Appear |
|                        |             | US-2004/0265385    | 12-30-2004                     | West   |   |
|                        | 1           | US-2005/085313     | 04-21-2005                     | Nishitani  |   |
|                        | I           | US-2005/0008672    | 01-13-2005                     | Winterbottom, et al.                               |   |
|                        |             | US-2005/0013793    | 01-20-2005                     | Beckham, et al.                                    |   |
|                        |             | US-2005/0159812 A1 | 07-21-2005                     | Dinger, III, et al.                                |   |
|                        |             | US-2005/0165128    | 07-28-2005                     | Cohn, et al.                                       |   |
|                        |             | US-2005/0177245 A1 | 08-11-2005                     | Leatherbury, et al.                                |   |
|                        |             | US-2005/0209705 A1 | 09-22-2005                     | Niederauer, et al.                                 |   |
|                        |             | US-2005/0240281 A1 | 10-27-2005                     | Slivka, et al.                                     |   |
|                        |             | US-2006/0067973 A1 | 03-30-2006                     | Schachter  |   |
|                        |             | US-2006/0136071    | 06-22-2006                     | Maspero, et al.                                    |   |
|                        | 1           | US-2006/0188547    | 08-24-2006                     | Bezwada  |   |
|                        |             | US-2006/0200150    | 09-07-2006                     | Homaki, et al.                                     |   |
|                        |             | US-2006/0178748 A1 | 08-10-2006                     | Dinger, III, et al.                                |   |
|                        |             | US-2006/0247610 A1 | 11-02-2006                     | Lanphere, et al.                                   |   |
|                        |             | US-2006/0263335    | 11-23-2006                     | France, et al.                                     |   |
|                        |             | US-2007/0041950 A1 | 02-22-2007                     | Leatherbury, et al.                                |   |
|                        |             | US-2007/0043376 A1 | 02-22-2007                     | Leatherbury, et al.                                |   |
|                        |             | US-2007/0128154    | 06-07-2007                     | Hadba, et al.                                      |   |
|                        | 1           | US-2007/0134305    | 06-14-2007                     | Zilberman  |   |
|                        | 1           | US-2007/0191963 A1 | 08-16-2007                     | Winterbottom, et al.                               |   |
|                        |             | US-2007/0240281 A1 | 10-27-2005                     | Slivka, et al.                                     |   |

|                       | <br>               |  |
|-----------------------|--------------------|--|
| Examiner<br>Signature | Date<br>Considered |  |

"EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant. \*Applicant's unique citation designation number (optional).\* See Kinds Codes of USPFO Patent Documents at <a href="https://www.updo.opg">www.updo.opg</a> or MPEP 901.04.\* Exter Office this issued the document, by the two-letter ode (MPO Standard ST.3).\* For Object this issued the document, by the two-letter ode (MPO Standard ST.3).\* The state of the patent document. \*Wind of document by the appropriate symbols as indicated on the document under MPO Standard ST. \*If possible.\*\* \*Populars is to place a other want here in the patent document. \*Wind of document by the appropriate symbols as indicated on the document under MPO Standard ST. \*If possible.\*\* \*Populars is to place a other want here in the patent document. \*Wind of document by the appropriate symbols as indicated on the document under MPO Standard ST. \*If possible.\*\* \*Populars is to place a other want here it if legislate its place and the control want to the patent and the patent

Intrastance in assertion.

Introduction of Information in Enquired by 27 CFR 197 and 1.98. The information is required to abbit or retain a benefit by the public which is to fig each by the confidence of the public which is to fig each by the public which is to fig each by the public which is to fig each by the public which is to complete, and or 25 CFR 1.41 This collection is estimated to table 2 house to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case, Any comments on the amount of time by un require to complete this form and/or supposed to the production of the public burshing the complete between the public burshing the complete between the public burshing the surface. However, the public burshing the public

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/08a (04-07)

Approved for use through 09/30/2007. (MB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it a collisis a valid UNB construction.

## Substitute for form 1449A/PTO Complete if Known 10/776409 Application Number INFORMATION DISCLOSURE Filing Date February 10, 2004 STATEMENT BY APPLICANT First Named Inventor Kelman Art Unit 3739 (Use as many sheets as necessary) Examiner Name Sheet of 7 Attorney Docket Number 10557/296452

|                       |              | FOREIGN PA  | ATENT DOCU                        | MENTS  |  |                |
|-----------------------|--------------|---|-----------------------------------|--|--|----------------|
| Examiner<br>Initials* | Cite<br>No.1 | Foreign Patent Document  Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>4</sup> (# known) | Publication<br>Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document                    | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|                       |              | WO 1990/003768  | 04-19-1990                        | Southern<br>Research Institute   |  |                |
|                       |              | WO 1995/034331 A1   | 12-21-1995                        | Aoforschungsinstit<br>ut Davos   |  |                |
|                       |              | WO 1997/005193 A1   | 02-13-1997                        | Sanitaria<br>Scaligera Spa   |  |                |
|                       |              | WO 1998/026814 A1   | 06-25-1998                        | JVS-Polymers Oy  |  |                |
|                       |              | WO 1999/011297 A2   | 03-11-1999                        | Univ. of<br>Nottingham   |  |                |
|                       |              | WO 2001/096105 A2   | 12-20-2001                        | Owens Corning<br>Fiberglass Corp.  |  |                |
|                       |              | WO 2002/076725  | 10-03-2002                        | Sicc   |  |                |
|                       |              | WO 2005/085313 A1   | 09-15-2005                        | Commonwealth<br>Scientific and<br>Industrial<br>Research<br>Organization |  |                |
|                       |              | WO 2006/053936  | 05-26-2006                        | JVS Polymers Oy  |  |                |
|                       |              | WO 2006/064025  | 08-24-2006                        | Fidia Advanced<br>Biopolymers  |  |                |
|                       |              | WO 2007/065074 A2   | 06-07-2007                        | Indiana Univ. Res.<br>And Tech. Corp.                                    |  |                |
|                       |              | WO 2007/084609 A2   | 07-26-2007                        | Osteotech, Inc.  |  |                |
|                       |              | EP 0 204 931 B2   | 12-17-1986                        | Biocon Oy  |  |                |
|                       |              | EP 0 401 844 B1   | 12-12-1990                        | Boehringer<br>Ingelheim<br>International                                 |  | Claims         |
|                       |              | EP 0 439 892 A2   | 08-07-1991                        | Kingston<br>Technologies, Inc.   |  |                |
|                       |              | EP 0 531 487 B1   | 01-10-1996                        | Storch   |  | Claims         |
|                       |              | EP 1 056 487 B1   | 12-06-2000                        | MIT .  |  |                |
|                       |              | EP 1 093 774 B1   | 06-19-2002                        | Karl Storz GmbH  |  | Claims         |
|                       |              | JP 2169612  | 06-29-1990                        | Asahi Chemical<br>Ind.   |  | Abstr          |
|                       |              | JP 8196617  | 08-06-1996                        | Takiron Co.  |  | Abstr          |
|                       |              | JP 9040761  | 02-10-1997                        | Shimadzu Corp.   |  | Abstr          |
|                       |              | JP 9095606  | 04-08-1997                        | Shinetsu<br>Chemical Co.   |  | Abstr          |
|                       |              | JP 9234241  | 09-09-1997                        | Shimadzu Corp.   |  | Abstr          |
|                       |              | JP 9272790  | 10-21-1997                        | Shimadzu Corp.   |  | Abstr          |
|                       |              | JP 9221539  | 08-26-1997                        | Shimadzu Corp.   |  | Abstr          |
|                       |              | JP 10176039   | 06-30-1998                        | Kanebo Ltd.  |  | Abstr          |
|                       |              | DE 39 36 188 A1   | 05-031990                         | Boehringer<br>Ingelheim  |  | Abstr          |
|                       |              | DE 42 26 465 A1   | 02-11-1993                        | Gunze Ltd.   |  | Abstr          |
|                       |              | KR 141988 B1  | 06-15-1998                        | Samyang Co. Ltd.   |  | Abstr          |

|           | <br>       |   |
|-----------|------------|---|
| Examiner  | Date       | 1 |
| Signature | Considered |   |

PTO/SS080(04-07)
Approved for use through 039/2002/07, OMB 0651-0305
U.S. Patent and Trademark. Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1985, no persons are required to respond to a collection of information unless contential valid CMB confort number.

|   | Substitute | for form 1449B/PTC | -      |            |                       | Complete if Known   |  |
|---|------------|--------------------|--------|------------|-----------------------|---------------------|--|
|   |            |                    | DIC    | OL OCUPE   | Application Number    | 10/776409           |  |
|   |            |                    |        | CLOSURE    | Filing Date           | February 10, 2004   |  |
|   | STAT       | EMENT B            | ΥA     | PPLICANT   | First Named Inventor  | Kelman              |  |
|   |            |                    |        |            | Art Unit              | 3739                |  |
|   |            | (Use as many she   | ets as | necessary) | Examiner Name         | Reimers, Annette R. |  |
| ↸ | Sheet      | 5                  | of     | 7          | Attomey Docket Number | 10557/296452        |  |

|                        |              | NON PATENT LITERATURE DOCUMENTS   |    |
|------------------------|--------------|---|----|
| Examiner<br>Initials * | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Τ² |
|                        |              | Andriano, et al., Processing and characterization of absorbable polylactide polymers for use in surgical implants,"<br>Journal of Applied Biomaterials, 5(2):133-140 (1994)   |    |
|                        |              | Asano, et al., "In vivo characteristics of low molecular weight copoly(D,L-lactic acid) formulations with controlled release of LH-RH agonist," <i>Biomaterials</i> , 10(8):569-573 (1989)  |    |
|                        |              | Barca, et al., 'Resorbable poly-L-factic acid mini-staples for the fixation of Akin osteotomies,' The Journal of Foot and Ankle Surgery, 36(2):106-111 (1997)   |    |
|                        |              | Bertrand, et al., 'Biocompatbility Aspects of New Stent Technology, JACC, 32(3):562-571 (1998)  |    |
|                        |              | Celikkaya, et al., 'Poly(DL-lactide)/Poly(ethylene glycol) Copolymer Particles. I. Preparation and Characterization,'<br>Journal of Applied Polymer Science, 61:1439-1446 (1996)  |    |
|                        |              | Frenger, 'Biomedical Uses of Shape Memory Polymers,' Biomed. Sci. Instrum., 29:47-50 (1993)   |    |
| -,                     |              | Fukuzaki, et al., 'Synthesis of copoly(D,L-Lactic acid) with relatively low molecular weight end in vitro degredation,<br>Japan Atomic Energy Research Institute, Gunma, Jpn, European Polymer Journal, 25(10):1019-1026 (1989)                                 |    |
|                        |              | Giardino, et al., 'Experimental evaluation of a resorbable intramedullary plug for cemented total hip replacement.'<br>Biomaterials, 18(13):907-913 (1997)  |    |
|                        |              | Gautier, et al., "Poly(ó-hydroxyacids) for application in the spinal cord: Resorbability end biocompetibility with edult rate Schwann cells and spinal cord," Journal of Biomedical Materials Research, 42(4):642-654 (1998)                                    |    |
|                        |              | Haers, et al., 'Biodegradable polyactide plates and screws in orthognathic surgery,' Journal of Cranio-Maxillofacial Surgery, 26(2):87-91 (1998)  |    |
|                        |              | Kaltian, et al., 'Poly(D,L-Lactic Acid) Homopolymers: Synthesis and Characterization,' Turkish Journal of Chemistry, 20:43-53 (1998)  |    |
|                        |              | Kister, et al., 'Effects of morphology, conformation and configuration on the IR and Raman spectra of various poly(lactic acid)s,' <i>Polymer</i> , 39(2): 267-273 (1998)   |    |
|                        |              | Koelling, et al., 'In vitro real-time aging and characterization of poly(L/D-lactic acid),' Proceedings of the 1997 16 <sup>th</sup> Southern Biomedical Engineering Conference (Cat. No. 97 <sup>th</sup> 3270), pp. 197-201                                   |    |

| Examiner<br>Signature  |  | Date<br>Considered |  |  |  |  |
|--|--|--------------------|--|--|--|--|
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. |  |                    |  |  |  |  |
| Include copy of this form with next communication to applicant.  |  |                    |  |  |  |  |

PTO/SB/08a (04-07)
Approved for use through 09/30/2007. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449A/PTO Complete if Known Application Number 10/776409 INFORMATION DISCLOSURE Filing Date February 10, 2004 CMENT DV ADDLICANT

| STATEMENT BY APPLICANT |  | First Named Inventor Kelman |           |                            |   |   |    |
|------------------------|--|-----------------------------|-----------|----------------------------|---|---|----|
|                        |  |                             |           |                            | Art Unit  | 3739  |    |
|                        | (Use as  | many she                    | ets as    | necessary)                 | Examiner Name   | Reimers, Annette R.   |    |
| Sheet                  | 6  |                             | of        | 7                          | Attorney Docket Number  | 10557/296452  |    |
|                        |  |                             |           | NON PATER                  | NT LITERATURE DOCUMENTS   |   |    |
| Examiner<br>Initials * | Cite<br>No.1                                     |                             |           | ook, magazine, jouma       |   | e article (when appropriate), title of<br>etc.), date, page(s), volume-issue<br>here published. | T² |
|                        |  |                             | ression   |                            |   | /D-lactide copolymers implants: study of<br>cience-Materials in Medicine, 9:10:603-             |    |
|                        |  |                             |           |                            | h-molecular weight polylactides by<br>hloride,' Polymer, 36(15):2995-30 | ring-opening polymerization with<br>03 (1995)   |    |
|                        |  | Losken                      | , et al., | 'Memory of DL-polylactic   | acid biodegradable plates,' Ann. I                                      | Plast. Surg., 32(6):606-611 (1994)  |    |
|                        | <del>                                     </del> | ManDay                      | oold o    | t al. 'Enzymatic degradati | elity of polydoctide): Effects of cha                                   | in storooghomistor and material   |    |

| Initials *            | No.1 | number(s), publisher, cit   |   |   | ' |  |  |  |
|-----------------------|------|---|---|---|---|--|--|--|
|                       |      | Kontio, et al., 'Fibrous wound repair associated with<br>the expression of tenascin and cellular fibronectin,' J<br>609 (1998)  | biodegradable poly-<br>lournal of Materials | L/D-lactide copolymers implants: study of<br>Science-Materials in Medicine, 9:10:603- |   |  |  |  |
|                       |      | Kricheldorf, et al., 'Polyactones: 32. High-molecular dibutylmagnesium or butylmagnesium chloride,' Poly  |   |   |   |  |  |  |
|                       |      | Losken, et al., 'Memory of DL-polylactic acid biodegr   | radable plates,' Ann.                       | Plast. Surg., 32(6):606-611 (1994)  |   |  |  |  |
|                       |      | MacDonald, et al., 'Enzymatic degradability of poly(li<br>crystallinity, ' Macromolecules, 29(23):7356-7361 (19   | actide): Effects of ch<br>996)              | ain stereochemistry and material  |   |  |  |  |
|                       |      | Mainil-Varlet, et al., 'Effect of in vivo and in vitro degi<br>low-molecular weight polylactides,' Journal of Biome   |   |   |   |  |  |  |
|                       |      | Matsumura, et al., 'Novel ring opening polymerization   | n of lactide by lipase                      | ," Macromol. Symp., 130:285-304 (1998)  |   |  |  |  |
|                       |      | Morita, et al., 'Intravitreous delivery of dexamethasor implants,' Biological & Pharmaceutical Bulletin, 21(2)  |   | enzoate from poly(DL-lactic acid)   |   |  |  |  |
|                       |      | Okihara, et al., 'Crystal structure of stereocomplex of poly(L-lactide) and poly(D-lactide), Journal of Macromolecular Science-Physics, B30(1-2):119-140 (1991)   |   |   |   |  |  |  |
|                       |      | Penning, et al., 'Preparation and properties of absort 951 (1993)   | bable fibres from L-la                      | actide copolymers, Polymer, 34(5):942-  |   |  |  |  |
|                       |      | Rak, et al., 'The preparation and characterization of Liverpool Polytech., Liverpool, UK, <i>Pharmaceutica A</i>  |   |   |   |  |  |  |
|                       |      | Ristic, et al., 'An investigation of synthesis and degradation of poly(D,L-lactide) and controlled release of albumin<br>from biodegradable poly(D,L-lactide) cylinders, 'LCheaP-2, the second Italian conference on chemical and process<br>engineering, Forence, pp. 558-583 (1995) |   |   |   |  |  |  |
|                       |      | Schliephake, et al., Reconstruction of the mandible by prefabricated autogenous bone grafts, Int. J. Oral Maxillofac. Surg., 26:244-252 (1997)  |   |   |   |  |  |  |
|                       |      | Stahelin, et al., 'Clinical degradation and biocompatibility of different bioabsorbable interference screws: a report of six cases,' Arthroscopy: The Journal of Arthroscopic & Related Surgery, 13(2):238-244 (1997)   |   |   |   |  |  |  |
|                       |      | Steendam, et al., The role of elastic relaxation in drug delivery from poly(DL-tactic acid) based tablets. A shape memory phenomenon, 'Proceedings of the International Symposium on Controlled Release of Bioactive Materials, 25-128-129 (1998)                                     |   |   |   |  |  |  |
| Examiner<br>Signature |      | _   | Date<br>Considered                          |   |   |  |  |  |

ith MPEP 609. Draw line through citation if not in conformance and not considered Include copy of this form with next communication to applicant. PTO/SIGIRS, (PL-07)
Approved for use through 08:03:02:07. ABG 0851-0351
U.S. Patent and Trademark-Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are regimed to respond to ordisord on information unless containing a valid CMR centrel number.

| 1                      | Substitute                       | for form 1449A/PTC   | ,      |            | Complete if Known      |                     |  |  |
|------------------------|----------------------------------|----------------------|--------|------------|------------------------|---------------------|--|--|
|                        |                                  |                      |        |            | Application Number     | 10/776409           |  |  |
|                        | INFO                             | RMATION              | DIS    | CLOSURE    | Filing Date            | February 10, 2004   |  |  |
| STATEMENT BY APPLICANT |                                  | First Named Inventor | Kelman |            |                        |                     |  |  |
|                        |                                  |                      |        |            | Art Unit               | 3739                |  |  |
|                        |                                  | (Use as many she     | ets as | necessary) | Examiner Name          | Reimers, Annette R. |  |  |
| Sheet 7 of 7           |                                  |                      |        |            | Attorney Docket Number | 10557/296452        |  |  |
| ſ                      | NON DATENT LITEDATIBLE DOCUMENTS |                      |        |            |                        |                     |  |  |

|                        |              | NON PATENT LITERATURE DOCUMENTS  |    |
|------------------------|--------------|--|----|
| Examiner<br>Initials * | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, dvj and/or country where published. | T² |
|                        |              | Stevels, et al., "Biends van blok copolymeren die een poly(L-lactide) of poly(D-lactide) blok bevatten," Biomedical Science and Engineering Meeting, pp. 107-110 (1994)  |    |
|                        |              | Tschakaloff, et al., Degradation kinetics of biodegradable DL-polyactic acid biodegradable implants depending on the site of implantation,' International Journal of Oral and Maxillofacial Surgery, 23(6 Pt2):443-445 (1994)                                  |    |
|                        |              | Tsuji, et al., 'Stereocomplex formation between enantiomeric poly(lactic acid). VIII. Complex fibers spun from mixed solution of poly(D-lactic acid) and poly(L-lactic acid), Journal of Applied Polymer Science, 51(2):337-344 (1994)                         |    |
|                        |              | Zegzula, et al., 'Bone Formation with Use of rhBMP-2 (Recombinant Human Bone Morphogenetic Protein-2,' The<br>Journal of Bone and Joint Surgery, 79:1778-1790 (1997)   |    |
|                        |              | Zhang, 'Blodegradable lactide polymers: synthesis, degradation, and controlled drug release properties (drug release), Queen's University at Kingston, Canada, Volume 55/01-B of Dissertation Abstracts International, p. i-xv, 1-178 (October 1993)           |    |

| Examiner<br>Signature | /David Comstock/ | Date<br>Considered | 11/20/2009 |
|-----------------------|------------------|--------------------|------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.